

May 28, 1999

Ms. Elizabeth Hiner, R.Ph.
Dockets Management Branch (HFA-305)
Docket No. 98-N-1265
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

By FAX: 301 443-2145 P1 29

I OPPOSE THE DRAFT M.O.U. being proposed by the FDA. In particular, I OBJECT to the definition of "inordinate amount" which restricts the availability and the right to obtain medically necessary compounded medications by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies.

Sally Q. Gates

May 28, 1999

Sally Q. Gates FAX: 706 323-0252 PHONE: 706 323-0252
1415 Big Eddy Court Columbus, Georgia 31904

COMMENTS: I am a 56-year-old female who had debilitating depression until I was fortunate enough to seek the help of the medical specialty which knows the most about hormone deficiencies, a Reproductive Endocrinologist. In 1988 he diagnosed my progesterone deficiency and prescribed natural progesterone tablets from Belmar Pharmacy in Lakewood, CO. This treated the CAUSE of my depression instead of the symptoms.

It was ten years later, in 1998, when the first natural progesterone products were approved by the FDA in the United States. If it were not for the compounding pharmacies and their ability to fill prescriptions, I would probably be in a Georgia facility for the mentally ill, since my money for private care would long ago have run out.

I am fortunate to have had the time and money to seek the help and expertise I needed to lead a normal and fulfilling life. It would be a tragedy for the FDA and congress to prevent women from receiving individualized hormone products. HRT in the US is still in the Dark Ages. The major drug companies do not currently have complete and safe products to offer women. Compounding pharmacies are doing an outstanding job helping doctors help their patients.

If you need further testimony on this issue, I would be happy to comply.